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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/986,376	11/08/2001	Dennis Colleran	00167-432001	5149

7590

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EXAMINER

WEBB, SARAH K

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 01/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/986,376

Applicant(s)

COLLERAN ET AL.

Examiner

Sarah K Webb

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10/18/02 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Drawings

1. The corrected or substitute drawings were received on 10/18/02. These drawings are approved by the draftsman.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-16 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In lines 5 and 6, claim 1 recites "*the member being movable between the first and second portions in a direction non-parallel to a direction of passage of the member through the opening*". Claim 1 recites limitations for "the member", yet "the member" is not part of applicant's invention. The dependent claims 2-16 are rejected as being dependent upon claim 1.

Claim 21 recites the limitation "the anchor body" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1,9-11,12,16,21, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,702,397 to Goble et al.

Goble includes all the limitations of claims 1,9-11,12,16,21, and 23. As most clearly illustrated in Figure 23, a bone anchor (135) includes a unitary central body and a restrictor. The anchor includes a plurality of bone penetrating tips (137). An opening (140) has a first portion (143) permitting passage of a member (27) and a second portion (144) restricting passage. The member (27) is moved between the first portion (143) and second portion (144) in direction non-parallel and *substantially* perpendicular to the direction of passage through the opening. Goble explains that the member (27) can be pulled through the first portion freely in one direction, but is locked in place if pulled in the opposite direction (column 11, line 61 through column 12, line 42).

As shown more clearly in Figure 10, the bone anchor includes a driver coupling (20), which is hexagonally shaped to accommodate a tool (column 8, lines 21-26).

Figure 6 shows the bone anchor (80) being driven by the tool (21).

Regarding claims 21 and 23 directed to the method of use, Goble describes the method of implanting the anchor in bone, which includes locking the sutures in the anchor, in columns 13 and 14.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 2-7, 18-20, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goble in view of US Patent No. 6,066,160 to Colvin et al.

Goble includes all the limitations of claims 2-7, 18-20, and 22, except for multiple oblique edges lining the wall of the opening of the bone anchor. Colvin discloses a suture securing apparatus (10) that includes a locking mechanism (18) with multiple oblique edges (20) lining an opening. A first portion (48) of the opening (14) allows passage of the member, or suture (16). The second portion (20) is smaller in diameter than the first portion and restricts passage of the sutures. Colvin explains that this structure allows passage of sutures in one direction, but opposes passage in the opposite direction (column 8, lines 62 – 64). The edges (20) are parallel to each other, which means they are also at the same angle relative the direction of suture passage.

Colvin gives support for including this suture locking mechanism as part of another device in lines 5-7 of column 8, as the main member may be incorporated as part of another prosthetic device, which could be a bone anchor. It would have been obvious to one of ordinary skill the art at the time the invention was made to substitute the suture locking edges of Colvin for the locking ball in the bone anchor of Goble, as this is an alternate way to prevent sutures from passing in an undesired direction through a device.

5. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goble in view of US Patent No. 5,782,866 to Wenstrom, Jr.

Goble includes all the limitations of claim 8, except for the opening being triangular in shape. Goble does show that sutures (27) can pass through a hexagonal

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opening (85) in Figure 5. Wenstrom teaches that openings in a bone anchor may be formed of various shapes, including curved edges and straight edges (Figures 1-6).

Wenstrom teaches that the various shapes serve as suture retaining structures (column 4, lines 4-5). Figure 5 shows an opening that includes a triangle-shaped portion. It would have obvious to modify the hexagonal opening of Goble to be a triangular opening, as Wenstrom teaches that an opening in a bone anchor can be formed of various shapes.

6. Claims 13-15, 17, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goble in view of US Patent No. 6,149,669 to Li.

Goble includes all the limitations of claims 13-15, except for multiple sharp resilient members. Li teaches that bone anchors (44) should include multiple sharp resilient members (48,49) for penetrating bone tissue to secure the anchor to bone (column 5, lines 45-49). The resilient members are able to move from a compressed position shown in Figure 1 to an expanded position shown in Figure 1A. It would have been obvious to one of ordinary skill the art at the time the invention was made to include multiple sharp resilient members, as taught by Li, in the bone anchor of Goble, as this structure forms a more secure attachment to bone.

Goble includes all the limitations of claims 17 and 24, but fails to connect a second bone anchor to the first bone anchor with a flexible member. As illustrated in Figures 1-5, Li teaches that multiple bone anchors can be attached by a flexible member, or suture (60). This system eliminates the cumbersome process of threading and manipulating sutures (column 1, lines 38 and 55). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use anchors of Goble in a

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system where multiple anchors are connected by a suture, as taught by Li, as this overcomes the complications associated with threading sutures.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6,355,066 to Kim and US 6,022,373 to Li disclose bone anchors with different types of resilient members. US 5,391,173 to Wilk discloses a suture locking device.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K Webb whose telephone number is (703) 305-7554. The examiner can normally be reached on 8am-4:30pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Sarah K Webb
Examiner
Art Unit 3731

SW
January 6, 2003


Michael Milano
Supervisory Patent Examiner
Art Unit 3700